administered for 10 days of the last third of the sequential administration.

34. The contraceptive combination of claim 31, in which the gestagen is selected from the group of compounds:

gestodene,
progesterone,
levonorgestrel,
cyproterone acetate,
chloromadinone acetate,
drospirenone (dihydrospirorenone),
norethisterone,
norethisterone acetate,
norgestimate,
desogestrel,
3-ketodesogestrel,
dienogest

or a mixture thereof.

35. The contraceptive combination of claim 31, in which the gestagen is contained in a daily dosage of:

0.05-0.2 mg of levonorgestrel,
0.05-0.15 mg of gestodene

or a bioequivalent dosage of another gestagen.--

REMARKS

Election

Applicants continue to vigorously traverse the restriction of Group I, drawn to a contraceptive process, and Group II, drawn to a kit to be used in the process of Group I. The two groups do, indeed, have unity of invention, because they contain the same special technical feature: the estrogen and gestagen components of the kit are designed to be administered in the same combinations, and under the same schedule of administration, as the estrogen and gestagen

components used in the claimed method. Furthermore, there is no serious additional burden imposed on Examiner to search the elements of the kit with the claimed methods. The search for the claimed method necessarily must take into account the materials administered and the manner in which these materials are administered. Thus, the subject matter of the kits will necessarily have already been searched in the search of the method of Group I.

Absent a serious burden on the Examiner, restriction is not proper. See MPEP §803. Merely, because the two groups are separately classified in the PTO does not mean the searches required for each group are not substantially the same or even identical. It is respectfully requested that the restriction requirement be withdrawn, and that the kit claims be examined with the method claims.

Applicants have also added new claims 31-35, which are drawn to "contraceptive combinations" which correspond to kit claims 8-12. These claims must be examined with the method claims, because PCT (371) rules mandate that a combination and method of using it be examined together. See, *e.g.*, 37 CFR §1.475: "(b)(2) A product and process of use of said product."

Withdrawn Rejection

The Examiner's withdrawal of the anticipation rejections in view of Gast (U.S. 5,747,480) and Konickx (U.S. 5,827,843) is acknowledged.

Rejections Under 35 USC § 103

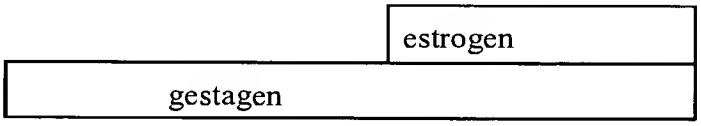
With regard to the obviousness rejections, applicants do not dispute that Gast, Koninckx, Neuman and the newly cited reference, Jager, disclose contraceptive methods which employ gestagens and estrogens. However, none of the references, taken together or separately, or knowledge available to one of skill in the art, discloses or suggests the particular manner in which these agents are combined, or the schedule of their administration, as recited in the instant claims. As is well known in the art, the levels of various hormones in female mammals vary during the menstrual cycle. Thus, for example, the levels of estrogen and progestogen, as well as other hormones, will vary cyclically in conjunction with the menstrual cycle. As a result, it is well known in the art of methods of hormonal therapy, especially contraception, that the dosage regimen, *i.e.*, the sequence and duration of administration of particular combinations of hormonal agents, is an important factor with regard to, *e.g.*, efficacy, potential side effects, patient compliance, and the like. Moreover, many of the disclosures within the art are devoted to using

different dosage regimens. Thus, the art doesn't recognize one particular dosage regime as being the optimal one. Furthermore, the very fact that two of the cited references are U.S. *patents* which claim contraceptive methods utilizing hormones (a gestagen and an estrogen) administered in different combinations and by different schedules, demonstrates the art's recognition that dosage regimen is not a more obvious choice, but instead is used to help distinguish different methods of hormonal therapy and help establish their individual patentability.

As demonstrated in Applicants' Reply of June 29, 2000 the references cited in the previous Office Action, Neuman, Friedmund, Gast and Konickx, do not disclose a contraceptive method in which the particular recited combinations are administered in the particular schedules recited in the instant claims. Nor do these references give any suggestion that would lead one of ordinary skill in the art to select combinations and dosage schedules recited in Applicants' claims. The conclusion that the claimed dosage regimens would be obvious without any demonstration within the art that these regimens are suggested is contrary to the art's overall teaching concerning the use of different dosage regimes.

The newly cited reference, Jager, also fails to disclose the method of the instant claims. For example, Jager does not disclose a method comprising a time period at the end of the administration cycle during which estrogen is administered. Rather, Jager administers progesterone and estrogen together during the first phase of administration, followed by a phase in which progesterone is the only active ingredient administered. See, *e.g.*, page 3, final paragraph or Example 3 (the example referred to by the Examiner). The following diagram graphically illustrates differences between Jager and the method of the instant invention.

Invention:



Jager:

The rejections fails to properly take into consideration the specific combinations and

dosage schedules recited in the instant claims. It is improper to simply dismiss features recited in the claims; claimed features cannot be ignored.

> We note at the outset that the claim limitation "to form *** hydroperoxides" must be given effect since we *must* give effect to *all* claim limitations. See In re Geerdes, 491 F.2d 1260, 180 USPQ 789 (CCPA 1974); In re Wilder, 57 CCPA 1314, 419 F.2d 447, 166 USPQ 545 (1970).

In re Angstadt et al., 190 USPQ 214, 217 (CCPA 1976).

This is particularly true for factors regarding dosage regimens in methods of contraception, for the reasons discussed above.

At best, the treatment in the rejection of the claimed combinations and schedules suggests that such aspects would be "obvious to try". However, it is well settled law that "obvious to try" does not constitute adequate motivation for an obviousness rejection. *Ex parte Argabright et al.*, 16 USPQ 703 (POBA 1967).

None of the references of record provides sufficient motivation to lead one of ordinary skill in the art to modify any of the methods of the cited references to achieve a method having a dosage regimen (combination and dosage schedule) in accordance with the claimed invention. An assertion of obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. To assess this determination, the hypothetical person has the relevant prior art references in from of him, but has **no knowledge of applicants' invention**. Motivation is not established simply assumed by piecing together disclosures in the prior art. It is more than this. Motivation describes the rationale as to why one would be directed toward making particular modifications. The more ability to combine parts of the prior art, by hindsight analysis, is not sufficient to establish motivation.

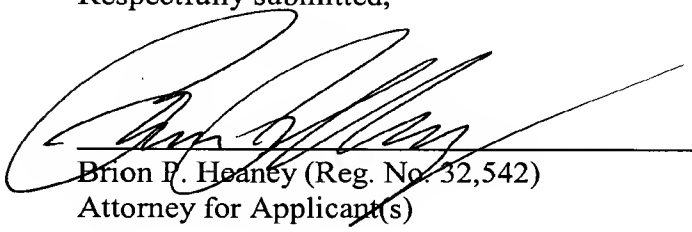
> ... As this court has stated, 'virtually all [inventions] are combinations of old elements ... Therefore, an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be an illogical and

inappropriate process by which to determine patentability. *In re Rouffet*, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998)

For the reasons discussed above, the prior art fails to establish obviousness of the claimed invention. In light of the absence of a *prima facie* case of obviousness, a "showing of criticality" is unwarranted and unnecessary.

In view of the preceding arguments, the application is believed to be in condition for allowance. Withdrawal of the prior art rejections and allowance of the application are respectfully requested.

Respectfully submitted,



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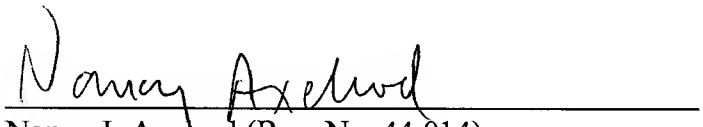

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Filed: January 16, 2001

BPH/NJA/lvb
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